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KRAMER LEVIN NAFTALIS & FRANKEL LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1177 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER
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SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3769

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 01152011

Application Number: 10/696,258  
Filing Date: October 28, 2003  
Appellant(s): Gomez, Rebecca

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Maria A. Taku  
For Appellant

**EXAMINER'S ANSWER**

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This is in response to the appeal brief filed August 20, 2010.

**(1) Real .Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application: 13-15, 19, 21, 27, 33-36, and 38-44.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

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**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg.

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Listing of Evidence Relied Upon**

The following is a listing of the evidence (e.g. patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
The Dilemma of Pilonidal Disease: Reverse Bandaging	Rosenberg	1977

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for Cure of the Reluctant  
Pilonidal Wound

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the length is at least twice or at least three times the width.

Claims 13-15, 19, 21, 27, 33-36, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg. Rosenberg teaches a device such as claimed except for the crescent shape and the rubber separation knobs. It would have been obvious to the artisan of ordinary skill to configure the device of Rosenberg in a crescent shape, since this is not critical; is well within the scope of one having ordinary skill in the art; provides no unexpected result; and would allow the device to more closely conform to the body of the user, and to lift the tissue at a particular angle, which is within the knowledge of one of ordinary skill in the art, as set forth above, and to employ rubber separation knobs on the devices of Rosenberg, since such knobs are known to provide better frictional engagement with compliant surfaces to which they are applied, thus producing a device such as claimed.

**(10) Response to Argument**

**A) The Declarations Filed Under 37 C.F.R. 1.132 Were Fully Considered**

Appellant argues that the Declarations by Doctors Steinhagen, Freed, and Curet, and the Declaration by Appellant Suarez were “improperly dismissed”. The examiner firstly notes that these Declarations were not “dismissed”, but were thoroughly evaluated and found insufficient to overcome the prima facie case of obviousness set forth by the examiner.

Beginning, appellant asserts that the Declarations by the three doctors express the views of those who are of ordinary skill in the art, and “expertly knowledgeable in the subject matter to which appellant’s claimed invention and Rosenberg pertain” (see the instant Brief, the second full sentence on page 9). The examiner does not dispute this determination.

Continuing, appellant argues that the examiner “has no basis to dismiss or overrule the declarations” inferring that the examiner has done so by merely reasoning that the examiner has found many similarities between the claimed invention and the Rosenberg device (see the instant Brief, the first sentence of the first full paragraph on page 9). The examiner vigorously traverses this inference. The examiner has not simply dismissed the assertions of Dr. Curet (the Declaration with regards to which the examiner made the statement regarding the similarities in the purpose, application, and design of the device of the instant claims and that of Rosenberg) out of hand, but has offered a detailed explanation of just what these similarities are (see the instant response, the last sentence of the paragraph bridging pages 4 and 5):

“both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize

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such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities”

For example, the examiner notes that the device of Rosenberg is employed to reduce friction that prevented healing of the wound (see the Final Rejection mailed February 22, 2010, the fourth through sixth sentences of the paragraph bridging pages 4 and 5):

“It is quite clear from the Rosenberg publication that “all factors causing friction in daily work habits prevented epithelialization” (see Rosenberg, page 290, column 1, second paragraph, third sentence) thus clearly Rosenberg identified friction as an impediment to the proper healing of the wound. Rosenberg also identified the solution to this problem – separation of the gluteal cleft (see Rosenberg, page 290, the paragraph beginning at column 2, second sentence). When faced with recalcitrant cases, which were determined to be resistant to treatment due only to “mechanical factors” (see the sentence bridging pages 290 and 291 of Rosenberg), Rosenberg determined to use adhesive strapping “on either side of the wound” wherein the “net effect was to flatten out the wound and remove most of the angle of the intergluteal clefts” (see page 291, column 1, first full paragraph). Clearly Rosenberg understood that the frictional engagement of the buttocks with the injured tissue was a barrier to proper healing, and that the solution was to tape the buttocks out of the way.”

This is precisely the effect that the instant device seeks to impart (see the originally filed disclosure, page 5, line 30 to page 6, line 9, and paragraph [0022] of the PreGrant Publication):

“These and other objects of the present invention are accomplished in accordance with the principles of the invention by providing methods and apparatus for alleviating pressure and friction due to rubbing from swollen areas of the body. In particular, the present invention provides a wearable device that, when worn, separates the swollen body area from other parts of the body. This reduces the amount of irritating friction that would otherwise occur, and it also tends to expose the inflamed area to the air to aide in the healing process by permitting drying to occur. The wearable device may be in the form of underwear (such as panties for women), or it may be in the form of single-use, partially adhesive, strips that perform the separate function. An additional feature of the underwear form of the present invention is the optional inclusion of a pocket for holding a cold compress or other treatment device in proper alignment with the affected area.”

Thus, as can be readily seen, Rosenberg has identified and seeks to solve the same problem as appellant has: the reduction of friction applied to the injured tissue by the motion of the buttocks during the course of normal activities. Further, as can be seen from the above, Rosenberg does this by using an adhesive structure to separate the buttocks from the wounded tissue. Thus this presents to the examiner that the Rosenberg device and the device of the instant claims are very similar “in the purpose, application, and design” thereof. The foregoing is also clearly produced by taking “into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made” (see the instant Brief, the third sentence of the first paragraph on page 9, citing MPEP 2145(X)(A), emphasis in original).

Next appellant argues that the examiner “has simply ignored the unsatisfied long felt need that applicant’s (sic, appellant’s) claimed invention addresses” (see the instant Brief, the sentence bridging pages 9 and 10). However, appellant has not demonstrated any “long felt need” with regard to the invention. The requirements for doing so are clearly set forth in MPEP 716.04 and include the production of an evidentiary showing, not only of the recognition of the problem solved by appellant (which problem has clearly been recognized by Rosenberg, as set forth above), but also attempts to solve the problem by others in the art, and their failure to do so. The current record bears no evidentiary showing of these factors, merely the assertion by appellant’s counsel that the need existed. It is well understood that “arguments of counsel cannot take the place of evidence in the record” (see *In re Schulze* 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) and MPEP 2145).



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Concluding, appellant asserts that the supplied Declarations are evidence that one of ordinary skill in the art would not regard the differences between appellant's claimed invention and Rosenberg as obvious, and asserts that the examiner's determination to the contrary constitutes improper hindsight reconstruction. The examiner must respectfully disagree. As set forth above, Rosenberg recognized the problem of the healing of injured tissue being impeded by friction from the buttocks, Rosenberg also recognized that this situation could be mitigated by using an adhesive device to pull the buttocks away from the injured tissue. Further, as set forth in the sentence bridging pages 13 and 14 of the Final Rejection mailed February 22, 2010, appellants own disclosure specifically states that the invention may take the form of "a single strip that is intended to stretch from one hip across the buttocks to the other hip (in which case each buttock would be attached), or a single strip that attaches to each buttock and wraps around the front of the affected individual" (see the originally filed disclosure, page 15, lines 14-19 and paragraph [0047] of the PreGrant Publication), i.e. the same form as the device of Rosenberg. Still further, as also set forth in the Final Rejection mailed February 22, 2010, the shape of the device is disclosed as not critical (see the second sentence of the last paragraph on page 12) "this shape is not critical, as set forth at page 13, lines 27-29 "Tape 30 may be made in any shape, such as the crescent-like shape shown in Figure 3, or other suitable shapes.". Given all of this; the fact that none of the Declarations discusses any type of comparative tests between the device of Rosenberg as contrasted with the claimed device to provide any objective evidence of the superior performance theorized by the various Declarants; and no objective evidence or assertion of unexpected results, the examiner is left with the conclusion that the claimed invention would

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have been obvious to one of ordinary skill in the art at the time of the invention in view of the teachings of Rosenberg.

#### **D) Anatomical Area Of Operation**

Pointing to the Declarations by the doctors mentioned above, appellant asserts that the “purpose of appellant’s claimed invention and the purpose of Rosenberg are different” (see the instant Brief, the first sentence of the last full paragraph on page 10), the evidence for this being the assertion in the Freed Declaration that the Rosenberg device operates on the periscaral skin and the subcutaneous tissue of the buttock to eliminate the natal cleft, while the claimed device operates to distract the buttocks to keep the skin of the perianal area from rubbing the inflamed tissue. However, nowhere does appellant or Declarant explain how the operation of the claimed device to prevent rubbing (i.e. friction) is fundamentally different from the operation of the Rosenberg device, which prevents friction, wherein the source of friction in each case is the buttocks.

Continuing appellant asserts that the examiner’s noting that the “different anatomical areas” operated on by the Rosenberg device and the claimed invention are only inches apart “is a red herring and insufficient for dismissing the declarations of the doctors” (see the instant Brief, the second sentence of the first full paragraph on page 11). Once again the examiner must point out that the Declarations were not “dismissed” rather fully considered and deemed non-persuasive. While both inventions act to separate the same body parts (both buttocks) for the same reason (to prevent friction), the fact that the location of the injury within the gluteal cleft is

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not in exactly the same spot does not negate the relevancy or the applicability of the Rosenberg teachings to the presently claimed invention. Further appellants example of operating on a section of the heart “only inches” from the area desired to be operated on is wholly incongruous with the example of parting the buttocks to prevent friction on a pilonidal cyst or a hemorrhoid.

Next appellant takes issue with the examiner’s noting that the natal cleft relates to the groove or crack between the buttocks that runs from below the sacrum to the perineum, by attempting to impeach the examiner’s source of the information (see the instant Brief, the paragraph bridging pages 11 and 12 and the first paragraph on page 12). However, the examiner must note that this is the only definition on record for the term “natal cleft” and appellant has chosen to provide no definition contradicting this. Rather, appellant, ironically, produces a definition of “perianal area” which is derived from the website [www.definition-of.com](http://www.definition-of.com), which website describes itself as a “community dictionary” wherein there is no indication that the definitions submitted are reviewed by even the undergraduates in biology, which appellant has derided as the arbiters of the source of the examiner’s definition. More to the point, this provides no evidence that the term “natal cleft” does not include the perianal area. And the examiner finds it strange, that with a person such as Dr. Freed, who “is more knowledgeable about this area of the human anatomy than the Examiner” (see the instant Brief, the first sentence of the paragraph bridging pages 12 and 13) at appellant’s disposal, that appellant should chose to consult a “community dictionary” for evidence that the natal cleft does not include the perianal area. For a careful reading of paragraph 7 (specifically the fourth sentence thereof) of the Freed Declaration reveals no such assertion, it merely states that the devices “operate in a different manner” not on a different area. Thus appellant’s assertion that the Freed Declaration states that

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“the natal cleft and the perianal area are different areas of the anatomy” (see the instant Brief, the last sentence of the paragraph bridging pages 12 and 13) is not supported by evidence of record, and as set forth more fully below, simply incorrect.

## **II) Declarations On Unique Structure And Comfort**

Next appellant turns to the Suarez Declaration, noting that the Declarant therein stated that the claimed invention allowed the wearer to stand, sit, walk, and engage in daily activities without discomfort. However, as set forth above, appellant has produced no comparative results expressed by individuals wearing a device as taught by Rosenberg to show objective evidence of greater comfort from the claimed invention than that of the device taught by Rosenberg (and the embodiment of the invention discussed at page 15 of the originally filed disclosure, discussed above). Again appellant relies upon arguments of counsel for this: “This is a unique result since generally, when a patient’s buttocks are being stretched apart and held separated, a patient cannot walk, sit, or move without discomfort and irritation” (see the instant Brief, the last sentence of the paragraph bridging pages 13 and 14). However as set forth above, this cannot take the place of objective evidence (see *In re Schulze* 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) and MPEP 2145).

Next, focusing on the claimed invention, appellant notes that the claimed crescent shaped form allows the patients buttocks to be lifted at a “very specific angle that follows the anatomy of the patient’s body” (see the instant Brief, the second sentence of the first full paragraph on page 14, and paragraph 7 of the Steinhagen Declaration). As mentioned in the Final Rejection,

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mailed February 22, 2010, the originally filed disclosure is completely devoid of any mention of any “specific angle” at which the tissue should be lifted, and thus any such angle must be known to one of ordinary skill in the art (see the first full paragraph on page 14):

“Continuing, applicant argues that (as set forth in the Declarations) that due to “the unique shape and structure, inflamed tissue caused by a hemorrhoid can be lifted at a specific angle that follows the anatomy of the patient’s body”. This argument is interesting, in that there is no mention whatsoever in the originally filed disclosure of lifting tissue “at a specific angle”. As this is nowhere discussed in the originally filed disclosure, this must be knowledge which is within the scope of one of ordinary skill in the art. As such, the knowledge of the desire to so lift the tissue, as well as the “specific angle” which is required would have been obvious to one of ordinary skill in the art.”

Continuing, appellant notes that the Steinhagen Declaration also discusses enhanced healing resulting from the lifting of the tissue at a specific angle. While this may be so, this does not render it unobvious to employ the device of Rosenberg in the manner and configuration (i.e. placing the linear tape in a curved configuration to produce the known “specific angle” as also set forth in the Final Rejection (see the paragraph spanning pages 7 to 9):

“Declarant’s statement in paragraph 6, that the device of Rosenberg is applied to a different part of the body than the claimed invention and is for a different purpose, noting that the claimed invention “includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids” may be true, it is also true that the “different part of the body” is only inches from the body part treated by applicant, and that the area still involves the buttocks. Further, it seems apparent that the device of Rosenberg, applied a few inches farther down the buttocks, would have the same effect as the device of applicant. The statement in paragraph 7 that “the claimed invention has a unique shape and structure not shown by Rosenberg” is noted, however, it is not clear, that the device of Rosenberg, properly applied by one of ordinary skill in the art of hemorrhoid treatment would not produce the same results, and thus would be able to “operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient’s body” and produce the “particular lifting” since this could be produced by separating the gluteal cleft so as to reduce or prevent mechanical friction (as taught to be desirable by Rosenberg, as set forth above) on the hemorrhoid. This

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would (via the shrinkage of the tissue due to the removal of the irritation caused by the friction from the buttocks during normal motion) “allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects of the inflamed tissue”. Further, there is no evidence that the device of Rosenberg “does not hinder movement of a patient’s body” which allows “a patient to walk, sit sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application” thereof. Indeed, the configuration of the device of Rosenberg is similar to a belt, which is well known in the art to allow a wearer to perform daily activities normally and in comfort. As to Declarant’s concluding assertion, which states that “Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention”, the examiner finds no correlation between the premise and the conclusion since, for example, a regular piece of tape, such as used by Rosenberg, could be affixed to the patient in a curvilinear manner (albeit with some portions of the tape not contacting the skin on the inner portion of the curve) and perform in the same way. Thus, the manner in which the “superiority” of the instant device over Rosenberg manifests itself is not clear, as it appears no comparative testing was done to determine the relative efficaciousness of the two devices. Thus while the assertion of superiority in paragraph 8 is noted, it remains only an assertion. Declarant’s opinion that the differences between the two devices would not be obvious, asserted in paragraph 9 are also noted. However, the legal test for obviousness is not whether the differences between two devices are obvious, but rather whether one of ordinary skill in the art would find it obvious to modify the prior art device to produce the claimed device, given the teachings of the prior art and the knowledge and level of skill of one of ordinary skill in the art. Thus while Declarant may find that “Rosenberg does not show the claimed invention”, the examiner notes that both devices seek to prevent mechanical friction on tissue which is healing; both devices do so by allowing the buttocks to be held separated, so as to minimize such friction; both devices effect this separation by employing adhesive elements that maintain the buttocks in a separated condition, while allowing the wearer to proceed with normal activities, the absence of similar products in the marketplace does not speak to the matter of non-obviousness, as this may be due to other factors, such as the ability of available surgical tape to perform the same function.”

As set forth above, if one of ordinary skill in the art were to apply the device of Rosenberg to produce the “specific angle” desired for hemorrhoid treatment and apparently known to one of ordinary skill in the art, since the angle is nowhere discussed in the originally filed disclosure, the same benefits would be provided. Thus appellant’s speculative assertion that the device of

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Rosenberg, if applied as Rosenberg teaches for pilonidal wound healing, were used for hemorrhoid treatment, would be uncomfortable is devoid of factual support on the record.

Similarly, as set forth above, the assertion that “applicant (sic, appellant) is unaware that a single doctor...has sought to use or even modify the Rosenberg reference” (see the instant Brief, the second sentence of the first full paragraph on page 16) is not a factual showing that such has not occurred.

### **III) Conclusion Regarding The Declarations**

The Declarations have been fully and thoroughly considered, and have neither been “ignored” nor “dismissed” as appellant contends. Having been given full consideration and the evidence presented therein fully evaluated and weighed against the teachings of Rosenberg, in combination with the knowledge of one of ordinary skill in the art, the showings of the Declarations are insufficient to overcome the prima facie case of obviousness set forth by the examiner.

### **B) Claims 13-15, 19, 21, 27, 33-36, And 38-44 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Rosenberg**

#### **Response To Arguments Regarding Claims 13 and 40**

Rosenberg teaches an adhesive device for treating pilonidal disease. The device of Rosenberg is admittedly a flat piece of tape, devoid of the crescent shape described in appellant’s

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claims. However, the device of Rosenberg, as set forth above, functions to adhesively engage the buttocks in order to hold them apart for the purpose of reducing or eliminating mechanical friction which exacerbates the injured area (the pilonidal cyst) and which would otherwise prevent healing of the affected tissue. This is precisely the mode of operation of the claimed invention: the instant device is used to adhesively engage the buttocks and hold them apart in order to reduce or eliminate the mechanical friction which would otherwise exacerbate the injured area (the hemorrhoid) which would otherwise prevent the healing of the affected tissue. Further the originally filed disclosure specifically states that the shape of the device is not critical: "Tape 30 may be made in any shape, such as the crescent-like shape shown in Figure 3, or other suitable shapes." (see the originally filed disclosure, page 13, lines 27-29 and paragraph [0044], second sentence of the PreGrant Publication) and the device may take the form of the device of Rosenberg: "a single strip that is intended to stretch from one hip across the buttocks to the other hip (in which case each buttock would be attached), or a single strip that attaches to each buttock and wraps around the front of the affected individual" (see the originally filed disclosure, page 15, lines 14-19 and paragraph [0047] of the PreGrant Publication). It is the examiner's view that one of ordinary skill in the art, would have been aware of the "specific angle" at which it is apparently desired for the buttocks to be held. This awareness is demonstrated by the complete absence of any discussion of a particular angle in the originally filed disclosure, in combination with original claim 21, which reads in pertinent part "... wherein said first and second strips of material are each pre-formed pieces of material configured such that, when applied to a person's body, they separate the buttocks to relieve discomfort caused by hemorrhoids" (wherein originally filed claims bear a strong presumption of an adequate written



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description, (see *In re Wertheim*, 541 F.2d 257,263, 191 USPQ 90, 97 (CCPA 1976) and MPEP 2163(I)(A))) . Given this awareness concerning the treatment of hemorrhoids, and with the teachings of Rosenberg, concerning the desirability of separating the buttocks with an adhesive device, in order to prevent mechanical friction and thereby allow wounded tissue between the buttocks to heal, employing an adhesive device which is crescent shaped, and with a length that is at least twice or three times the width would have been obvious to one of ordinary skill in the art at the time the invention was made.

As appellant correctly notes, the Rosenberg device does not have the crescent shape claimed. And further relies on the submitted Declarations to refute the examiner's reasoning as to the obviousness to one of ordinary skill in the art of providing the crescent shape. However, none of the Declarations aver, nor is there any other evidence of record that the Declarants therein are disinterested third parties. While they clearly have credentials qualifying them as being of at least ordinary skill, there is no evidence of record that there is no advantage, either financially, or in the realm of professional prestige, to Declarants regarding the issuance of the instant claims. Further still, there were no comparative tests conducted to determine the relative effectiveness and/or comfort of the Rosenberg device and the claimed invention, thus the conclusions drawn, even by those of ordinary skill, are of necessity based on speculation and opinion, rather than fact.

Continuing, appellant again asserts a long felt need for the claimed invention. However, as set forth above, appellant has supplied no evidentiary showing to this effect, and this is not convincing.

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Next appellant asserts that appellant disagrees with the examiner's assessment that the specific angle, which is not discussed in the originally filed disclosure, but is referred to in the Steinhagen Declaration, is knowledge which is within the scope of one of ordinary skill in the art (see the instant Brief, the second paragraph on page 22). But, in the subsequent paragraph, appellant appears to reverse this assertion, stating "the mentioning of the specific angle in Steinhagen's declaration is the doctor's expert observation on the manner in which the claimed invention operates" (see the instant Brief, the first full sentence on page 23). Clearly, if the doctor observed this angle as part of the operation of the claimed invention, the claimed invention must have been applied by someone in such a manner as to produce this angle. Thus whoever applied the device, be it Declarant, a nurse or other health professional, or the patient themselves, **someone** knew the specific angle at which to place the tissue and did so, since appellant has designated the various physician Declarants each as being one of ordinary skill in the art (see the instant Brief, the first full sentence on page 9), the angle was known either by Declarant Steinhagen (i.e. one of ordinary skill in the art) or one having less than ordinary skill in the art (e.g. a nurse or other health professional, or the patient themselves), thus demonstrating that the knowledge was clearly within the scope of one of ordinary skill in the art.

Further appellant argues that "Rosenberg is designed for application to a different part of the body for treating a different disease" (see the instant Brief, the first sentence of the paragraph on pages 23 and 24), asserting this as an indicia of non-obviousness. However, as set forth above, the device of Rosenberg functions to adhesively engage the buttocks in order to hold them apart for the purpose of reducing or eliminating mechanical friction which exacerbates the injured area (the pilonidal cyst) and which would otherwise prevent healing of the affected

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tissue. The is precisely the mode of operation of the claimed invention: the instant device is used to adhesively engage the buttocks and hold them apart in order to reduce or eliminate the mechanical friction which would otherwise exacerbate the injured area (the hemorrhoid) which would otherwise prevent the healing of the affected tissue. Thus Rosenberg is clearly analogous art, as it is at least reasonably pertinent to the particular problem with which the applicant was concerned (see *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992)). And as such would not be ignored by one of ordinary skill in the art, despite appellant's contention that it operates on a different part of the body. However, it is further noted that Rosenberg is concerned with treating wounds that reach into the intergluteal cleft (see Rosenberg, page 291, the last sentence of the first full paragraph: "The net effect of this was to flatten out the wound and remove most of the angle of the intergluteal cleft"). According to the Freedman Declaration, the Rosenberg device operates on the natal cleft. The "natal cleft" is defined as "the sulcus between the buttocks (nates). SYN crena ani" (Stedman's Medical Dictionary, 26th Edition), while "sulcus" is defined as "any long narrow groove, or slight depression" (Stedman's Medical Dictionary, 26th Edition); and "crena ani" is defined as "the anal cleft; the cleft between the buttocks on which the anus opens" (Dorland's Illustrated Medical Dictionary, 27<sup>th</sup> Edition). Thus clearly, the natal cleft includes that area of the body including the anus, which is the site of hemorrhoids. Therefore, assertions that the device of Rosenberg operates on "a different part of the body" or "a wholly different part of the anatomy" than the claimed invention are not well founded.

### **Response To Arguments Regarding Claim 33**

Here appellant again notes the lack of disclosure regarding the crescent shape in Rosenberg. The examiner refers to the response to this argument set forth in the section concerning claims 13 and 40. Also appellant argues that Rosenberg fails to show a “tab” as claimed and that the examiner has not identified such a feature in the prior art. The examiner firstly notes that the word “tab” does not appear in the originally filed disclosure. As such the term is given its broadest reasonable interpretation. The term “tab” is defined as “a projection, flap, or short strip attached to an object to facilitate opening, handling, or identification” (The American Heritage Dictionary). Thus the end of the piece of adhesive strapping of Rosenberg is considered to fulfill the recitation of the tab.

**C) Claims 13-15, 19, 21, 27, 33-36, And 38-44 Are Properly Rejected Under 35 U.S.C. 112, First Paragraph As Failing To Comply With The Written Description Requirement**

Regarding the length verses width limitation, appellant argues that Figure 3 supports this limitation. However, there is not indication in the originally filed disclosure that the device be limited to this configuration. As set forth above, the originally filed disclosure actually states that the device can by “any shape”, thus this limitation is deemed to be new matter.

**D Objection To The Amendment Filed November 12, 2009**

This is a petitionable matter (see MPEP 1002.02(c)(3)(c)) and is not properly before the Board (see MPEP 1201).

**(11) Related Proceedings Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

**(12) Conclusion**

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/

David Shay  
January 17, 2011

Conferees  
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